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FIRST NAMED INVENTOR ATTORNEY DOCKET NO. FILING DATE APPLICATION NO. 09/289,321 04/09/99 BACHOVCHIN 19644-010 **EXAMINER** HM22/0901 IVOR R. ELRIFI LUKTON, D PAPER NUMBER MINTZ LEVIN ART UNIT ONE FINICIAL CENTER 1653 BOSTON MA 02111 DATE MAILED: 09/01/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 09/289,321

Examiner

Bachovkin

Group Art Unit 1653



	David Lukton	1653	
X Responsive to communication(s) filed on Mar 24, 2000			
☐ This action is FINAL .			
Since this application is in condition for allowance except in accordance with the practice under Ex parte Quayle3			
A shortened statutory period for response to this action is set longer, from the mailing date of this communication. Failure application to become abandoned. (35 U.S.C. § 133). Exten 37 CFR 1.136(a).	to expire 30 DAYS		
Disposition of Claim			
X Claim(s) <u>1, 17, 35, 39, 49, 51, 52, and 56-70</u>		ialara nandi	
Of the above, claim(s)		israte pendi	ng in the applicat
Claim(s)		s/are withdrawn	from consideration
Claim(s)		is/are	allowed.
☐ Claim(s)		is/are	rejected.
☐ Claim(s)		is/are	objected to.
Claims <u>1, 17, 35, 39, 49, 51, 52, and 56-70</u>	are subject to	restriction or ele-	ction requirement.
Application Papers			
☐ See the attached Notice of Draftsperson's Patent Drawi	ng Review, PTO-948.		
The drawing(s) filed on is/are	objected to by the Examiner.		
The proposed drawing correction, filed on	is approved	disapproved.	
☐ The specification is objected to by the Examiner.			
The oath or declaration is objected to by the Examiner.			
Priority under 35 U.S.C. § 119			
Acknowledgement is made of a claim for foreign priority	under 35 U.S.C. § 119(a)-(d).		
☐ All ☐Some* None of the CERTIFIED copies o	f the priority documents have be	en	
received.	, , , , , , , , , , , , , , , , , , , ,		
☐ received in Application No. (Series Coc's/Serial No	umber)		
received in this national stage application from the	International Bureau (PCT Rule	¹ • 17 2(a))	
*Certified copies not received:		2(4)).	
 Acknowledgement is made of a claim for domestic priori 	ty under 35 U.S.C. § 119(e).		
attachment(s)	- (,		
☐ Notice of References Cited, PTO-892			
☐ Information Disclosure Statement(s), PTO-1449, Paper N	o(s)		
☐ Interview Summary, PTO-413			
☐ Notice of Draftsperson's Patent Drawing Review, PTO-94	8		
☐ Notice of Informal Patent Application, PTO-152			
			1
SEF OFFICE ACTION ON	THE FOLLOWING PAGES		
	THE FULLUWING PAGES		

Pursuant to the directives of paper No. 4 (filed 4/9/99), claims 2-16, 18-34, 36-38, 40-48, 50, 53-55 have been cancelled, and claims 57-70 added. Claims 1, 17, 35, 39, 49, 51, 52, 56-70 are pending.

*

A restriction is imposed, as set forth below. First however, the following subgenera are defined:

G1: The structure of each substituent variable is specifically disclosed in the specification, or is sufficiently defined in the specification so that one of ordinary skill would recognize what structure is intended.

G2: The structure of any one (or more) substituent variable cannot be determined without consulting a U.S. Patent or other reference that has been cited in the specification. Compounds of genus G1 are excluded from this group.

G3: R¹ is a boronate group, and the compounds of G2 are excluded.

G4: R1 is a phosphonate group, and the compounds of G2 are excluded.

G5: R1 is a fluoroalkylketone group, and the compounds of G2 are excluded.

G6: R¹ is an alpha-keto amide or an alphaketo acid group, and the compounds of G2 are excluded.

Restriction to one of the following inventions is required under 35 U.S.C. §121:

- 1. Claims 1 and 35, drawn to compounds which bear two or more boronic acid groups,
- 2. Claim 17, drawn to a genus of compounds, with the proviso that that G2 is excluded
- 3. Claim 17, drawn to a genus of compounds, with the proviso that that G1 is excluded.
- 4. Claim 39, drawn to a method for activating lymphocytes by use of a compound according to Group 1.
- 5. Claim 39, drawn to a method for activating lymphocytes by use of a compound according to Group 2.
- 6. Claim 39, drawn to a method for activating lymphocytes by use of a compound according to Group 3.
- 7. Claim 56, drawn to a method for treating an autoimmune condition by administering a compound of Group 1.
- 8. Claim 56, drawn to a method for treating an autoimmune condition by administering a compound of Group 2.
- 9. Claim 56, drawn to a method for treating an autoimmune condition by administering a compound of Group 3.
- 10. Claims 57-70, drawn to mixtures of compounds which are limited solely and exclusively to genus G2.
- 11. Claims 57-70, drawn to mixtures of compounds which are limited to G3.
- 12. Claims 57-70, drawn to mixtures of compounds which are limited to G4.

- 13. Claims 57-70, drawn to mixtures of compounds which are limited to G5.
- 14. Claims 57-70, drawn to mixtures of compounds which are limited to G6.
- 15. Claims 57-70, drawn to mixtures of compounds which can be whatever the claims permit, provided that subgenera G2, G3, G4, G5 and G6 are excluded.

Claim 56 in part (to the extent that it encompasses claim 49) and claims 49, 51-52 are withdrawn from consideration at this time, since "L" is undefined. However, a new restriction which includes claims 49 and 51-52 will be issued if both of the following conditions are met: (a) applicants state that they want to elect an invention that is encompassed by claim 49, and (b) applicants amend claim 49, in response to this Office action, to define substituent "L". If only one of these two conditions is met, however, a new restriction will not be issued.

The claimed inventions are distinct.

Genus G2 has been created because of the perceived potential for applicants to try to create a genus of compounds, or a list of specific compounds which are not explicitly recited in the specification. The specification has not been examined thoroughly, but there might be a statement to the effect that a given variable "X" can encompass substituents that are disclosed in, e.g., U.S. Patent 1,234,567. Applicants could then attempt to create a new genus that could not have been foreseen from a reading of the specification. Applicants

are free to do this, but the "window of opportunity" for this course of action will close after the first action on the merits. If the situation is "borderline", applicants are urged to amend the specification (to incorporate the referenced material) <u>prior</u> to the first Office action on the merits. On the other hand, if applicants have no intention of amending the specification to "extract" out information that is contained within a referenced document, then applicants can simply ignore all mention of genus G2.

Inventions 1-3 and 4-9 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP 806.05(h)). Nevertheless, in the event that claims are elected which are drawn to compounds or compositions, and claims therein found allowable, the corresponding method-of-use claims will be rejoined for further examination [*In re Ochiai* (37 USPQ2d 1127)].

In addition to the foregoing, rejoining of one or more of the non-elected groups is not precluded. In fact, applicants may indicate a second and third choice for examination among the non-elected groups.

Applicant is advised that for the response to this requirement to be complete, an election of the invention to be examined must be indicated, even if the requirement is traversed (37 C.F.R. 1.143).

Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

In addition to the foregoing, applicants are required under 35 U.S.C. §121 to elect a disclosed specie for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. A "specie" is a specific compound, with all substituent variables accounted for. In the case of Groups 8-13, two separate elections are required. The first is a "specie" is a specific compound that is contained within the mixture; the second is specie is a second compound, which is different from the first. Claim 57 mandates the presence of a library; one cannot have a library without at least two compounds being present in the mixture.

Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a generic claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are witten in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentable distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103 of the other invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton. Phone: (703) 308-3213.

An inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

DAVID LUKTON PATENT EXAMINER GROUP 1999